[PHYSICIAN’S LETTERHEAD]

[MD NAME]

[CENTER] [ADDRESS] [CITY STATE ZIP]

[DATE]

Dear Dr. [NAME]:

I’d like to report FDA approval of a therapy for untreatable atrial fibrillation (AF) patients. Hybrid AF™ Convergent Therapy is now approved in the United States to treat **long-standing persistent AF patients** (who are in AF for 12 months or longer).

In your practice, you see patients who suffer from AF. We now offer this therapy in our practice, and I would like to share some data about the Hybrid AF Convergent procedure. Until now, effective treatment has been extremely limited for this category of AF patients.

Atrial fibrillation is the most commonly diagnosed arrhythmia in the U.S., with 1 in 4 adults over 40 developing AF in their lifetime. AF affects over 33 million people worldwide, and about 8 million people in the United States. Approximately 45% of AF patients have long-standing persistent AF, which affects more than 3.5 million patients in the United States.

If AF is not properly treated, it leads to a higher risk of chronic fatigue, decreased activity level, diminished quality of life, and sudden death. Moreover, AF imparts a 5x higher risk of both stroke and heart failure.

Because AF is a steadily progressive condition, patients should receive optimal treatment before their arrhythmia worsens.

\*New 18-month data showed that in the Hybrid AF Convergent arm (compared to the endocardial radiofrequency RF ablation arm):

* Therapy was **2.3x** more effective
* Patients were **> 2x** as likely to be off antiarrhythmics

In addition, the recently FDA-approved therapy showed a **≥ 90%** reduction in burden for most patients (79%) at 1 year.

Patients enrolled in the Hybrid AF CONVERGE study:

* had AF that lasted more than 1 year,
* were refractory or intolerant to one antiarrhythmic drug,
* had left atrial size < 6.0 cm,
* were between ages > 18 and < 80 years.

In the CONVERGE trial, primary safety data show adverse events of:

* 2.9% at 7 days (not pre-specified by protocol, in-line with endocardial studies),
* 7.8% at 30 days (pre-specified CONVERGE protocol),

CONVERGE Safety Events (full cohort): No deaths, atrioesophageal fistulas, or cardiac perforations.

30 Day: Protocol pre-specified definition

* 1 Stroke (slightly slower left facial movement, did not have debilitating effect)
* 1 Phrenic nerve injury (PNI), resolved
* 1 Bleed
* 1 Bleed with late pericardial effusion
* 1 Transient ischemic attack (TIA)
* 4 Cardiac Tamponade

Incorporating both endocardial RF and epicardial therapies, the Hybrid AF Convergent procedure targets two key areas where AF originates and creates transmural lesions that stop the onset of AF. This therapy may provide a long-term solution for appropriately selected patients with long-standing persistent AF. See the indications below.

I hope that as you evaluate patients in your daily practice, you consider referring patients who may be candidates for this procedure.

**Your patients with long-standing persistent AF may exhibit these symptoms: dyspnea • dizziness • hypotension • weakness • fatigue • angina • tachyarrhythmias or palpitations**.

If you have any questions, want more information about the procedure, or would like to discuss a specific case, please contact me directly at <PHONE/EMAIL>. I look forward to working with you to offer an option to patients who are seeking treatment for their long-standing persistent AF.

\*Data based on the post-hoc analysis of long-standing persistent AF sub-groups (N=65)

**EPi-Sense® Guided Coagulation System**

**Indications**: The EPi-Sense® Guided Coagulation System with VisiTrax® is intended for the coagulation of cardiac tissue using radiofrequency (RF) energy during cardiac surgery for the treatment of arrhythmias including Atrial Fibrillation (AFIB) or Atrial Flutter (AFL).

**Contraindications:** Patients with presence of left atrial thrombus, a systemic infection, active endocarditis, or another infection local to the surgical site at the time of surgery. Patients with Barrett’s Esophagus.

Sincerely,

[PHYSICIAN NAME]

[TITLE]

[INSTITUTION]